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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,275

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EXAMINER

KLINKEL, KORTNEY L

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,275	<b>Applicant(s)</b> PARK ET AL.	
	<b>Examiner</b> Kortney Klinkel	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,14 and 15 is/are rejected.
- 7) ☒ Claim(s) 2,3,14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/20/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claims***

Claims 1-15 are pending in the instant Office action.

Applicant's election of Group II, claims 2, 3, 14 and 15 in the reply filed on May 12, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore claims 1, and 4-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Accordingly, claims 2, 3, 14 and 15 are under consideration in the instant Office action.

### ***Information Disclosure Statement***

Acknowledgement is made of applicant's submitting an information disclosure statement on April 20, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner. The following two documents are not in English and as a result, only their English Abstracts have been considered, KR 2001-0011241 and Tokunaga, K., et al., Fragrance Journal, 1993, pages 51-56.

### ***Foreign Priority***

Acknowledgement is made of applicant's foreign priority claim to Republic of Korea patent application serial number 10-2003-0068932 filed March 31, 2006 and to Republic of Korea patent application serial number 10-2004-0075864 filed March 31, 2006. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

The amendment to the Specification on March 31, 2006 incorporating the continuity information and the claim to foreign priority has been received and acknowledged.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because current figures 1-10 and 14 are of poor quality and are exceedingly difficult to read. Specifically, in Figure 1, the key indicates five lines are present in the graph, however, only three are discernable. Figures 2-4 are photographs supposedly showing a photoaging inhibitory effect of sphingomyelin, however, the three

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photographs are so dark and grainy it is impossible to discern a difference between them. Figure 5 is a photograph showing the results of skin histological test. The series of three photographs is of acceptable quality, however, the figure as well as the description of the figure is lacking description of what the individual photographs represent. Without this description, it is not clear what message Applicant's are attempting to convey with Figure 5. Figures 6-10 are presented to illustrate the wound repairing effect of sphingomyelin, however the photographs are of such poor quality that it is impossible to discern what they represent. Figure 14 consists of a series of photographs showing a skin wrinkle improving effect of sphingomyelin, however, the photographs are so grainy and/or washed out that it is exceedingly difficult to discern a difference between the pairs of photographs. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Objections***

Claims 2-3, and 14-15 are objected to for having an unnecessary article. The claims recite inhibiting a skin aging or a skin photoaging. The unnecessary article "a" implies that there is more than one kind of skin aging or photoaging.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3, and 14-15 provide for the use of a composition, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 2-3 and 14-15 depend on the composition of withdrawn claim 1. In order to expedite prosecution, the composition will be examined as if it pertains to a composition for protecting skin comprising sphingomyelin as an active ingredient.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-3 and 14-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process

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claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

**NOTE:** For the purpose of expediting examination, Examiner is interpreting the “use claims”, claims 2-3 and 14-15, as method of use claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4 and 14-15 rejected under 35 U.S.C. 102(b) as being anticipated by Greff et al. (New Cosmetic Compositions Containing Sphingomyelins and Other Complex Lipids, FR 2692781, as per the certified English translation. Both the English translation and underlying French document have been included in the file).

Greff teaches cosmetic compositions containing sphingomyelins from fat globules of milk as precursors of ceramide (page 4). Cream A, which comprises milk fat globule lipids, which contain between 5 and 35 % sphingomyelin (pages 4-5) was used on 20 volunteers for 3 weeks. The volunteers saw improved skin state, including faded wrinkles, less dry and less stretched skin. Wrinkles and stretched result from aging and photoaging.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-3 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5702688).



Yu teaches a composition for therapeutic as well as preventive measures for cosmetic conditions and dermatologic disorders by topical application (abstract). The composition comprises sphingomyelin (column 5, lines 30-31 and claim 1). The dermatologic disorders can be skin sun damage and skin changes associated with aging (see Test 10, column 32, lines 25-67, also claim 9).

The teaching of Yu differ from the instant application in that sphingomyelin is one of 45 compounds listed as potential active ingredients in the composition. However, it would have been obvious to use sphingomyelin in a skin care composition to inhibit skin aging and photoaging to one of ordinary skill in the art at the time of the instant invention with a reasonable expectation of success because sphingomyelin is listed with a finite number (45) of identified, predicable solutions.

Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected sphingomyelin from the finite group of 45 listed compounds in claim 1, to arrive at the compositions of the instant invention with a reasonable expectation of success.

Claims 2-3, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naru et al. (US PGPub 2004/0033246) and further in view of Colombaioni et al. ("Sphingolipid Metabolites in Neural Signalling and Function" Brain Res. Rev. 46, 2004, 328-355, as per Applicant's IDS) as further evidenced by Mao-Qiang et al. (Journal of Investigative Dermatology, 106(5), 1996, pages 1096-1101).

Applicant's claim the use of a composition comprising sphingomyelin as the active ingredient, for inhibiting skin aging (claim 2), inhibiting skin photoaging (claim 3), wherein the composition is a composition for oral administration or topical application (claims 14-15).

With respect to claims 2 and 3 Naru teach a cosmetic for preventing skin aging, including skin aging from exposure to ultraviolet rays, which Examiner is interpreting to be a form of photoaging, containing L-histidine and ceramide as an active ingredient (abstract, and specifically Examples 1, 2 and 4). The compositions are for topical use in the form of creams and lotions.

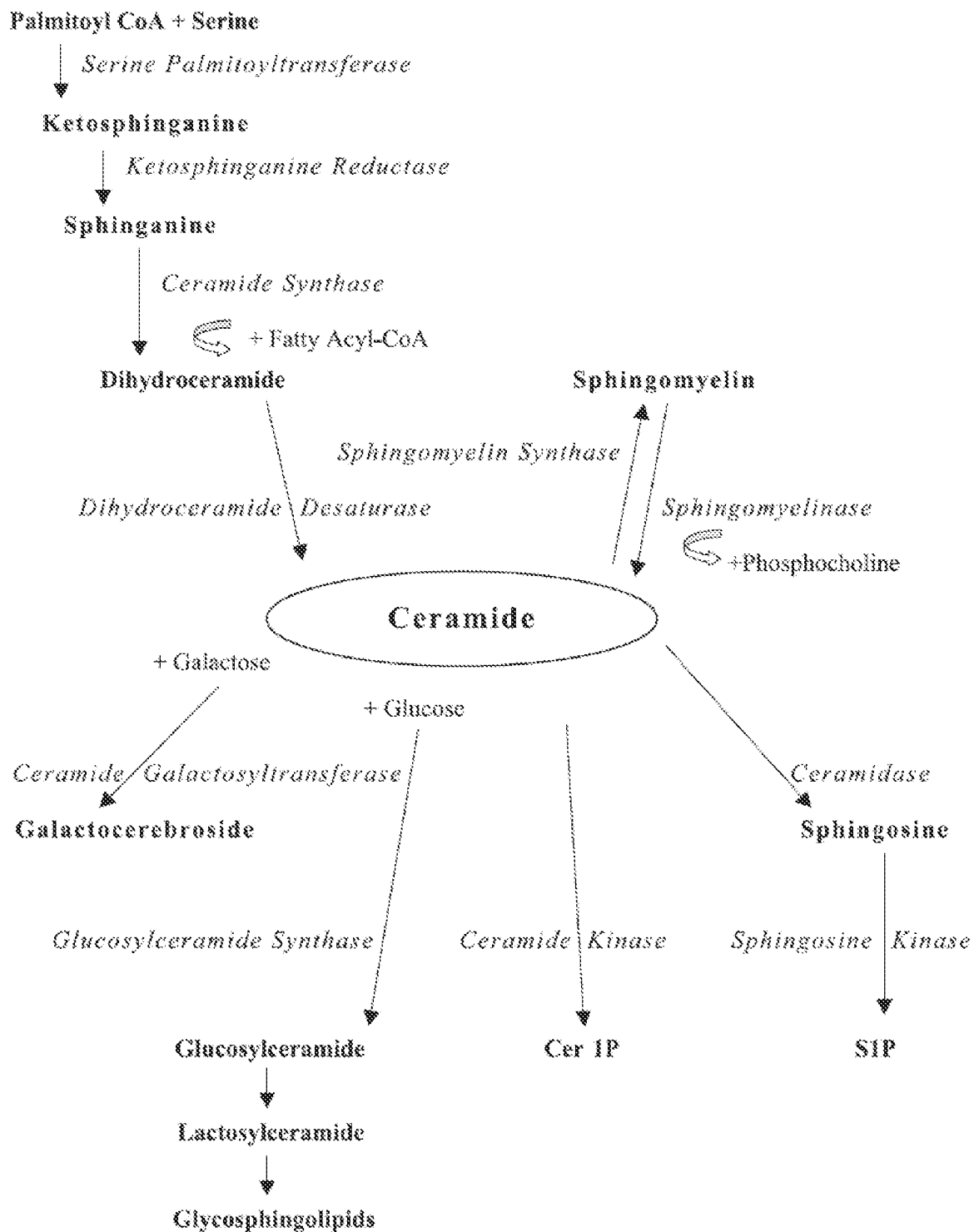
The teachings of Naru differ from the instant invention in that the active ingredient of Naru's composition is ceramide and that of the instant invention is sphingomyelin. This difference is overcome by the teachings of Colombaioni.

Colombaioni teach the metabolic pathways of sphingolipids. Figure 2, from page 330 has been pasted in below in order to illustrate the direct connection between ceramide and sphingomyelin. Sphingomyelin and ceramide are readily interconverted through the action of sphingomyelinase, which is a readily available skin enzyme. With respect to Figures 2 and 3, Colombaioni state, "It is clear from these figures that the

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metabolites are interconvertible and this makes [it] complex to determine the specific role of each one.” Figure 2 is shown below and it illustrates the connection between sphingolipids.

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Due to the facile interconversion of sphingomyelin to ceramide via the skin enzyme, sphingomyelinase, introducing sphingomyelin to the skin will necessarily convert a portion of the sphingomyelin to ceramide. Conversely, introducing ceramide to the skin will necessarily convert a portion of the ceramide to sphingomyelin. Sphingomyelin can be thought of as a precursor to ceramide.

Mao-Qiang et al., cited here to illustrate a fact, state that sphingomyelin is a phospholipid precursor of ceramide (page 1099). Mao-Qiang also show that within statistical error, sphingomyelin, under identical conditions, exhibits the same barrier recovery time as ceramide. Mao-Qiang's discussion, suggests that the active agent, even when sphingomyelin alone is applied, is ceramide. These findings suggests that sphingomyelin and ceramide are functional equivalents.

Based off the above teachings an artisan of ordinary skill in the art would be motivated to utilize sphingomyelin as a functional equivalent/precursor of ceramide. Therefore, it would be *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to substitute sphingomyelin for ceramide with a reasonable expectation for success.

Applicant's data presented in the specification (Examples 1-2) has been considered. Due to the natural conversion of sphingomyelin to ceramide, there is no way to disprove that ceramide is in fact the active ingredient regardless of whether sphingomyelin or ceramide is administered. Likewise, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to substitute sphingomyelin for ceramide with a reasonable expectation for success.

***Conclusion***

Claims 2-3 and 14-15 are rejected, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, Ph.D. whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615